Exhibit A

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TO:	**Examiners Mitra and Dr. Weber**		
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FROM:	**Joseph R. Baker, Jr.**		
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Message

Patent
Attorney's Docket No. 1034123-000096

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	**MAIL STOP AF**
Mohamed Zaiou *et al.*	Group Art Unit: 1653
Application No.: 10/815,562	Examiner: MITRA, RITA
Filed: March 31, 2004	Confirmation No.: 5767
For: THERAPY FOR MICROBIAL INFECTIONS	Certificate of Mailing DRAFT NOT FOR ENTRY INTO THE FILE

Talking Points for Telephonic Interview

Dear Examiners Mitra and Dr. Weber:

Please consider the following:

IN THE CLAIMS:

In response to the Final Office Action, claims 2 and 13 were canceled to make for addition of New claims 23 and 24.

LISTING OF CLAIMS

1. (Withdrawn) An isolated cationic cathelin-like peptide having antimicrobial activity and comprising an amino acid sequence:
(Q/R)X_1(L/P)SY(K/R)(E/D)AVLRA(V/I)$X_2X_3X_4$N(E/Q)(Q/R)S(S/L)(D/E)X_5NLYRLLX_6L(D/N)X_7X_8PX_9X_{10}(D/E)X_{11}DPX_{12}(T/I)(P/R)K(P/S)V(S/R)F(T/R)VKETVC(P/G)(K/R)X_{13}(T/E)(Q/R)QX_{14}(P/L)EX_{15}CX_{16}FK$X_{17}X_{18}$G(L/R)VK(Q/R)CX_{19}G(A/T)V(T/I)L(D/N)$X_{20}X_{21}$ $X_{22}X_{23}X_{24}$(F/L)D(I/L)(N/S)C(N/D)$X_{25}X_{26}X_{27}X_{28}X_{29}X_{30}X_{31}$ (SEQ ID NO:3), wherein X1 is A, V or T; X2 is N, D or G; X3 is G, R, D or Q; X4 is L, I or F; X5 is E, A or T; X6 is Q, E or D; X7 is S, Q or P; X8 is Q, P, R, E or A; X9 is K, T, Q or N; X10 is G, A, M or D; X11 is G, E or V; X12 is N, G or D; X13 is P, T or A; X14 is P, S or L; X15 is Q, L, D or E; X16 is G, D or A; X17 is D, E or K; X18 is N, D or Q; X19 is E, V or M; X20 is E, P or Q; X21 is D, S or A; X22 is T, I, R, A or N; X23 is G, H or D; X24 is S, Y or Q; X25 is S, E or K; X26 is I, D, A or L; X27 is L, Q or N; X28 is S, P, K or Q; X29 is V, F or R; X30 is R, F or K; and X31 is F, A, R or K

2. (Canceled)

3. (Previously Presented) A method for inhibiting the growth of a bacterium or yeast comprising contacting the bacterium or yeast with an inhibiting effective amount of a peptide consisting of an amino acid sequence as set forth in SEQ ID NO:2 from about amino acid 31 to 131.

4. (Previously Presented) The method of claim 3, wherein the bacterium is gram positive.

5. (Previously Presented) The method of claim 3, wherein the bacterium is gram negative.

6. (Previously Presented) The method of claim 3, further comprising contacting the bacterium or yeast with at least one antimicrobial agent.

7. (Previously Presented) The method of claim 6, wherein the antimicrobial agent is selected from the group consisting of a β-lactam, novobiocin, polymyxin B, and LL-37.

8. (Previously Presented) The method of claim 3, wherein the contacting is *in vitro*.

9. (Previously Presented) The method of claim 3, wherein the contacting is *in vivo*.

10. (Previously Presented) The method of claim 9, wherein the contacting is by topical administration.

11. (Withdrawn) A peptide having from about 96 to about 100 amino acids and including a sequence shown in SEQ ID NO:3, wherein X1 is A, V or T; X2 is N, D or G; X3 is G, R, D or Q; X4 is L, I or F; X5 is E, A or T; X6 is Q, E or D; X7 is S, Q or P; X8 is Q, P, R, E or A; X9 is K, T, Q or N; X10 is G, A, M or D; X11 is G, E or V; X12 is N, G or D; X13 is P, T or A; X14 is P, S or L; X15 is Q, L, D or E; X16 is G, D or A; X17 is D, E or K; X18 is N, D or Q; X19 is E, V or M; X20 is E, P or Q; X21 is D, S or A; X22 is T, I, R, A or N; X23 is G, H or D; X24 is S, Y or Q; X25 is S, E or K; X26 is I, D, A or L; X27 is L, Q or N; X28 is S, P, K or Q; X29 is V, F or R; X30 is R, F or K; and X31 is F, A, R or K

12. (Withdrawn) A pharmaceutical composition for therapy of bacterial infections and/or disorders comprising a peptide selected from the group consisting of:

(a) a peptide comprising a sequence

(Q/R)X_1(L/P)SY(K/R)(E/D)AVLRA(V/I)
$X_2X_3X_4$N(E/Q)(Q/R)S(S/L)(D/E)X_5NLYRLLX_6L(D/N)X_7X_8PX_9X_{10}(D/E)X_{11}DPX_{12}(T/I)(P/R)K(P/S)V(S/R)F(T/R)VKETVC(P/G)(K/R)X_{13}(T/E)(Q/R)QX_{14}(P/L)EX_{15}CX_{16}FK$X_{17}X_{18}$

G(L/R)VK(Q/R)CX_{19}G(A/T)V(T/I)L(D/N)$X_{20}X_{21}X_{22}X_{23}X_{24}$(F/L)D(I/L)(N/S)C(N/D)$X_{25}X_{26}X_{27}X_{28}X_{29}X_{30}X_{31}$ (SEQ ID NO:3),

wherein X1 is A, V or T; X2 is N, D or G; X3 is G, R, D or Q; X4 is L, I or F; X5 is E, A or T; X6 is Q, E or D; X7 is S, Q or P; X8 is Q, P, R, E or A; X9 is K, T, Q or N; X10 is G, A, M or D; X11 is G, E or V; X12 is N, G or D; X13 is P, T or A; X14 is P, S or L; X15 is Q, L, D or E; X16 is G, D or A; X17 is D, E or K; X18 is N, D or Q; X19 is E, V or M; X20 is E, P or Q; X21 is D, S or A; X22 is T, I, R, A or N; X23 is G, H or D; X24 is S, Y or Q; X25 is S, E or K; X26 is I, D, A or L; X27 is L, Q or N; X28 is S, P, K or Q; X29 is V, F or R; X30 is R, F or K; and X31 is F, A, R or K; and

(b) a peptide comprising a sequence as set forth in SEQ ID NO:2 from about amino acid 31 to 131,

in a pharmaceutically acceptable carrier.

13. (Canceled)

14. (Withdrawn) The composition of claim 12 in a liposomal form.

15. (Withdrawn) The composition of claim 12 in a lyophilized form.

16. (Withdrawn) The composition of claim 12 in a unit dosage form.

17. (Withdrawn) The composition of claim 12 in an aerosol form.

18. (Withdrawn) The composition of claim 12 in a foam.

19. (Withdrawn) A method of alleviating symptoms of a bacterial infection in a subject, comprising administering an effective amount of an N-terminal active fragment of a cathelicidin-derived peptide comprising a sequence as set forth in SEQ ID NO:2; or a peptide comprising a sequence as set forth in SEQ ID NO:3, wherein X1 is A, V or T; X2 is N, D or G; X3 is G, R, D or Q; X4 is L, I or F; X5 is E, A or T; X6 is Q, E or D; X7 is S, Q or P; X8 is Q, P, R, E or A; X9 is K, T, Q or N; X10 is G, A, M or D; X11 is G, E or V; X12 is N, G or D; X13 is P, T or A; X14 is P, S or L; X15

is Q, L, D or E; X16 is G, D or A; X17 is D, E or K; X18 is N, D or Q; X19 is E, V or M; X20 is E, P or Q; X21 is D, S or A; X22 is T, I, R, A or N; X23 is G, H or D; X24 is S, Y or Q; X25 is S, E or K; X26 is I, D, A or L; X27 is L, Q or N; X28 is S, P, K or Q; X29 is V, F or R; X30 is R, F or K; and X31 is F, A, R or K, to the subject.

20. (Withdrawn) The method of claim 19, wherein said administering is selected from the group consisting of: intravenous, intramuscular, intradermal, subcutaneous, intracranial, intracerebrospinal, topical, oral, transdermal, transmucosal and transnasal.

21. (Withdrawn) A method of promoting tissue repair and regeneration in a subject comprising contacting an injured tissue with a composition comprising a peptide selected from the group consisting of:

(a) a peptide comprising a sequence (Q/R)X_1(L/P)SY(K/R)(E/D)AVLRA(V/I)$X_2X_3X_4$N(E/Q)(Q/R)S(S/L) (D/E)X_5NLYRLLX_6L(D/N)X_7X_8PX_9X_{10}(D/E)X_{11}DPX_{12}(T/I)(P/R)K(P/S)V (S/R)F(T/R)VKETVC(P/G)(K/R)X_{13}(T/E)(Q/R)QX_{14}(P/L)EX_{15}CX_{16}FKX_{17} X_{18}G(L/R)VK(Q/R)CX_{19}G(A/T)V(T/I)L(D/N)$X_{20}X_{21}X_{22}X_{23}X_{24}$(F/L)D(I/L)(N/S)C(N/D)$X_{25}$ $X_{26}X_{27}X_{28}X_{29}X_{30}X_{31}$ (SEQ ID NO:3),

wherein X1 is A, V or T; X2 is N, D or G; X3 is G, R, D or Q; X4 is L, I or F; X5 is E, A or T; X6 is Q, E or D; X7 is S, Q or P; X8 is Q, P, R, E or A; X9 is K, T, Q or N; X10 is G, A, M or D; X11 is G, E or V; X12 is N, G or D; X13 is P, T or A; X14 is P, S or L; X15 is Q, L, D or E; X16 is G, D or A; X17 is D, E or K; X18 is N, D or Q; X19 is E, V or M; X20 is E, P or Q; X21 is D, S or A; X22 is T, I, R, A or N; X23 is G, H or D; X24 is S, Y or Q; X25 is S, E or K; X26 is I, D, A or L; X27 is L, Q or N; X28 is S, P, K or Q; X29 is V, F or R; X30 is R, F or K; and X31 is F, A, R or K; and

(b) a peptide comprising a sequence as set forth in SEQ ID NO:2 from about amino acid 31 to 131.

22. (Currently Amended) A method for inhibiting the growth of a bacterium or yeast comprising contacting the bacterium or yeast with an inhibiting effective amount of a cathelin-like peptide or variant consisting essentially of an amino acid

sequence as set forth in SEQ ID NO:2 from about amino acid 31 to 131, wherein the cathelin-like peptide or variant is a cysteine proteinase inhibitor and/or exhibits antibacterial activity.

23. (New) The method of claim 22, wherein the cathelin-like peptide variant has 1-10 conservative amino acid substitutions between amino acid 31 and 131 of SEQ ID NO:2.

24. (New) The method of claim 22, wherein the cathelin-like peptide or variant consists of about 104 amino acids.

REMARKS

Claims 1-21 are pending in the application. Claims 1, 2, and 11-21 are withdrawn from consideration as being drawn to non-elected matter. Claims 2 and 13 have been canceled without prejudice to Applicants' right to prosecute the canceled claims in any continuation, continuation-in-part, divisional or other application. Claims 3-10 have been indicated as allowable. Claim 22 is rejected. Claim 22 has been amended herein to further clarify the invention. Claims 23 and 24 have been added as dependent claims from claim 22. The amendments are fully supported by the specification as set forth below and in paragraphs [0037]-[0039]. In addition, the amendments and new claims do not introduce new matter requiring a further search as the Examiner has already searched the scope of claim 22, upon which claims 23 and 24 depend.

REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claim 22 stands rejected under 35 U.S.C. §112, first paragraph, because the specification while being enabling for a method for inhibiting the growth of a bacterium or yeast comprising contacting the bacterium or yeast with an inhibiting effective amount of a peptide consisting of an amino acid sequence as set forth in SEQ ID NO:2 from about amino acid 31 to 131, allegedly does not reasonably provide enablement for a method for inhibiting the growth of a bacterium or yeast comprising contacting the bacterium or yeast with any peptide consisting essentially of an amino acid sequence as set forth in SEQ ID NO:2 from about amino acid 31 to 131. The Examiner maintains this rejection in the Advisory Action mailed August 4, 2006.

The Examiner is construing "consisting essentially of" as being open ended. Applicants respectfully submit that the scope of "consisting essentially of" limits the scope of a claim to the specified materials or step "and those that do not *materially* affect the *basic* and *novel* characteristic(s) of the claimed invention. *In re Herz*, 537 F. 2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). MPEP §2111.03 goes on to state, "For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims or what the basic and novel characteristics actually are, 'consisting essentially of' will

be construed as equivalent to 'comprising'." Applicants submit that the specification identifies the novelty of the claimed invention thus providing a "clear indication in the specification" as to what the basic and novel characteristics of the invention. As identified in MPEP §2111.03, the claims for purposes of searching "consisting essentially of" are to be construed with reference to the specification. For example, the specification indicates at paragraph

In this regard, Applicants submit that the specification clearly sets forth the basic and novel characteristics such that the scope of the claims can be properly determined based upon the specification and the transitional phrase "consisting essentially of". For example, the specification states:

> [0033] As used herein, the term *"cationic cathelin-like peptide' refers to a chain of amino acids that is about 96 to about 104 amino acids in length and comprises a sequence as set forth in SEQ ID NO:3 or the N-terminal cathelin-like domain of SEQ ID NO:2. . . .*

Claim 22 as amended reads:

> 22. A method for inhibiting the growth of a bacterium or yeast comprising contacting the bacterium or yeast with an inhibiting effective amount of a ***cathelin-like peptide*** or variant consisting essentially of an amino acid sequence as set forth in SEQ ID NO:2 from about amino acid 31 to 131, wherein the cathelin-like peptide or variant is a cysteine proteinase inhibitor and/or exhibits antibacterial activity.

Accordingly, the specification indicates what the basic and novel characteristics actually are for interpreting "consisting essentially of". From the specification it is clear that the cathelin-like domain/peptide is novel and functional. In addition, the specification defines the cathelin-like domain/peptide sufficiently that one of skill in the art would recognize the scope of "consisting essentially of" in the claims including functional variants (see, e.g., paragraphs [0037-0039]).

In the advisory action, the Examiner indicates that it would require undue experimentation to determine what variant or peptide consisting essentially of SEQ ID NO:2 from about amino acid 31 to 131 would have function. Applicants respectfully submit that variants (e.g., the cathelin-like peptide having 1-10 conservative amino acid substitutions) do not require undue experimentation to assay. Simply put, generate the peptide and contact it with a microbe/bacteria and determine the peptide's killing effect. Such assays are very routine.

Applicants would also consider providing the following claim should the Examiner prefer:

25. (New) A method for inhibiting the growth of a bacterium or yeast comprising contacting the bacterium or yeast with an inhibiting effective amount of a cathelin-like peptide or variant consisting essentially of an amino acid sequence of 96 to 104 amino acids in length and containing the sequence as set forth in SEQ ID NO:2 from about amino acid 31 to 131, wherein the cathelin-like peptide or variant is a cysteine proteinase inhibitor and/or exhibits antibacterial activity.

For the reasons set forth above, it is believed that this case is in condition for allowance. Applicants accordingly request that this Amendment be entered and that the rejections under 35 U.S.C. §112 be carefully reconsidered. In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that the prosecution of this application may be expedited.

Respectfully submitted,
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